



PATENT
Docket No. 473912000100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Benjamin D. Pless

Serial No.: 09/629,242

Filing Date: July 31, 2000

For: PROCEDURES FOR PHOTODYNAMIC
CARDIAC ABLATION THERAPY AND
DEVICES FOR THOSE PROCEDURES

Examiner: H. Johnson

Group Art Unit: 3739

RECEIVED
MAY 13 2004
TECHNOLOGY CENTER 3700

**DECLARATION OF BENJAMIN D. PLESS
PURSUANT TO 37 C.F.R § 1.131**

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Benjamin D. Pless, declare as follows:

1. I am the sole inventor in the above-referenced patent application, and am familiar with the contents of that application.

2. I understand that the claims in my application are being rejected as unpatentable over the disclosure in Publication No. US 2002/0095197A1 to Lardo et al. ("the Lardo application"), and the provisional patent application to which the Lardo patent claims priority, which was filed on July 11, 2000. I also understand that the filing date of my application is legally presumed to be the date upon which the devices and methods in my claims were reduced

to practice. Finally, I understand that this declaration is simply to show, based on the attached written evidence, that I had completed at least as much of my claimed devices and methods as is shown in the Lardo application.

3. Prior to July 11, 2000, I had formed a complete and operative idea of the photodynamic cardiac ablation therapy methods and devices claimed in the subject application. At my direction, E. Thomas Wheelock (Reg. No. 28,825) of Morrison & Foerster LLP prepared a utility patent application disclosing this invention, which application was filed in the United States Patent and Trademark Office on July 31, 2000 (U.S. Patent Application No. 09/629,242, "Procedures for Photodynamic Cardiac Ablation Therapy and Devices for Those Procedures"). The following paragraphs summarize the documents attached to this declaration which are submitted as evidence of these statements. All of the attached documents were prepared in the United States.

4. *Exhibit A* is a photocopy of a document entitled "invention disclosure" as delivered to my patent attorney, E. Thomas Wheelock (Reg. No. 28,825) of Morrison & Foerster LLP, prior to July 11, 2000. This document was prepared in the U.S. prior to July 11, 2000. In Exhibit A, the dates (all of which are prior to July 11, 2000) and the portions of the document that are not relevant to this declaration have been obscured. The text of Exhibit A shows the steps of a method for producing patterned lesions in cardiac tissue by subjecting cardiac tissue containing a photodynamic drug to a specific light source, where the light source is arranged to produce a lesion in a pattern corresponding to the light source. Paragraph 3 of the section entitled "Summary of the invention" states, "a patient is given the photodynamic drug prior to the ablation procedure. During the procedure, a catheter or other device containing a light source, or light guides (typically fiber optics) connected to a light source, is placed on the heart in the area that the physician wants to create a lesion. The heart is then illuminated with high intensity light, triggering the photodynamic reaction in the localized area where the lesion is desired."

Exhibit A further shows the steps of providing a device for providing light to cardiac tissue containing a photodynamic drug to create lesions on that cardiac tissue. Paragraph 4 (referring to Figure 2) of the section entitled "Detailed description" states, "Figure 2 shows a

device to deliver light from a light source to the epicardium of the heart... At the distal end, the fiber optics terminate in an elongated window that allows light to escape. The back side of the window (18) is opaque to ensure that no light escapes to reach tissues other than those targeted by the physician," showing that I had possession of the complete concept of utilizing a light emitting device for photodynamic cardiac ablation in which a transparent region could be used to transmit light to cardiac tissue to form a patterned lesion and devices for accomplishing that method.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

April 20, 2004

Benjamin D. Pless

Benjamin D. Pless